11. Stability study

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND. (GUJ.)	DEPARTMENT	Doc. No.	BQE442
	QUALITY CONTROL	Revision	00
		Supersedes	NEW
		Page	1 of 14
TITLE	STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG		

Distribution	Controlled copy
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COPY 8 – PURCHASE	☐
COPY 9 – DISPATCH	☐

Effective Date:	04 JAN 2011	
Training Category	Class room training	☐
	On job training	☑
	Read and understood	☐

FUNCTION	NAME	DESIGNATION	SIGNATURE	DATE
Prepared by	Darshan S. Shah	Q.C. officer		01/01/2011
Reviewed by	Harshad B. Patel	Q.C. Executive		02/01/2011
Approved by	Vinod A. Patel	Q.C. manager		02/01/2011
Authorized by [QA]	Shereafatali S. Saiyed	QA Head		02/01/2011

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1.0 PURPOSE:

The purpose of this stability study protocol is to conduct study of Amoxicillin For Oral Suspension USP 250mg initial three consecutive batches and one yearly batch. This is required to provide evidence on how the quality of the drug product varies with time under the influence of environmental factors such as temperature & Humidity and also enables recommended storage conditions, retest periods and shelf life to be established.

2.0 SCOPE:

This protocol gives details about generation of stability data in the given primary packaging material for Amoxicillin For Oral Suspension USP 250mg initial three consecutive batches (Initial / Non routine Stability Study) as well as for one yearly batch (Ongoing / Routine Stability Study) manufactured at Baroque Pharmaceuticals Pvt. Ltd., 192/3, Sokhada- 388 620, Khambhat. This protocol prepared with generic name of product and applicable to all brand name products having same manufacturing formula and primary packaging material.

3.0 REFERENCES:

SR. NO.	CODE	TITLE
1	TRS 863	WHO Technical Report Series, No. 863, Annex 5.
2	Q1A (R2)	ICH Stability Testing of New Drug Substances and Products.

4.0 RESPONSIBILITY:

DESIGNATION	RESPONSIBILITY
QC Officer / Executive	To prepare stability protocol and report. To sample required quantity of samples as per approved protocol. To store stability sample as per storage condition & chambers. Responsible for performing the analysis as per the shelf life specification as well as schedule.
Officer / Executive QA	To review stability protocol. To ensure that stability samples withdrawn as per protocol. To ensure that stability study is performed as per stability protocol and SOP for stability study.

DESIGNATION	RESPONSIBILITY
QC Head	To approve the stability study protocol. To conduct training. To review stability report data for its completeness and correctness. To approved stability report.
Head QA	To authorized the stability study protocol and report.

5.0 MATERIALS AND EQUIPMENT:

- Stability Chambers:
  Chamber Condition: $30^0C \pm 2^0C$ / 65% RH ± 5% RH
  Chamber Condition: $40^0C \pm 2^0C$ / 75% RH ± 5% RH
- Others are as per the Requirement

6.0 ABBREVIATIONS AND DEFINITIONS:

6.1 ABBREVIATIONS:

TERM	EXPLANATION
TRS	Technical Report Series
ICH	International Conference on Harmonization
°C	Degree Centigrade
%RH	Percentage Relative Humidity
AC	Accelerated Condition
LT	Long Term

6.2 DEFINITIONS:

TERM	EXPLANATION
Stability	The term with respect to a drug dosage form refers to the chemical & physical integrity of the dosage unit & when appropriate, the ability of the dosage unit to maintain protection against microbial contamination.
Accelerated testing	Studies designed to increase the rate of chemical degradation or physical change of a drug substance or drug product by using exaggerated storage conditions as part of the formal stability studies.
Long term testing	Stability studies under the recommended storage condition for the re-test period or shelf life proposed (or approved) for labeling.
Shelf life	The time period during which a drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.

7.0 GENERAL INSTRUCTION:

7.1 Introduction

Generic Name of Product: Amoxicillin For Oral Suspension USP 250mg

Label Claim of Product:

After reconstitution each 5ml contains:

Amoxicillin USP (As Trihydrate)

Eq. to Amoxicillin 250mg

Excipients Q.S

Colour: Erythrosine

7.2 Composition:

Batch Size : 10,000 Bottles

Sr. No.	L. C. / 5 ml (mg)	Ove %	INGREDIENTS	Specific -ation	Item Code	A.Q.R./ B
			MIXING			
1.	250.000	-	Amoxicillin Trihydrate Eq. to Amoxicillin (B)*	USP	100006U	30.000
2.	1326.370	-	Sucrose (Pharma Grade) (D)$	BP	B101027B	159.164
3.	4.000	-	Sodium Methyl Paraben	BP	B101022B	0.480
4.	8.500	-	Xanthan Gum FNCS	BP	B101051B	1.020
5.	11.100	-	Sodium Benzoate	BP	B101019B	1.332
6.	2.100	-	Disodium EDTA	BP	B101007B	0.252
7.	27.800	-	Colloidal Anhydrous Silica	BP	B101001B	3.336
8.	0.700	-	Erythrosine Colour	IHS	B104002B	0.084
9.	36.100	-	Pineapple Flavour	IHS	B106005B	4.332

Reference number of Batch Manufacturing Record: BQE/MFR/442

United State Pharmacopeia

BP : British Pharmacopeia

IHS: In-house Specification

L. C. / 5 ml = Label Claim per 5 ml

A.Q.R/B = Actual Quantity Required Per Batch

% Ove = Overages in %.

Qty. Req./ 5 ml = Quantity Required per 5 ml

(B)* = Quantity to be calculated on the basis of its potency

(D)$ = Quantity to be compensated on increasing quantity of active material and its L.O.D.

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7.0 GENERAL INSTRUCTION:

7.3 Ongoing / Routine stability study:

In case of *routine stability*, samples of one batch per product (In case of different brand name packed of same generic product, Stability study of one brand can be applicable to all brand name products having same primary packing material) per year shall be kept for *long-term stability study*.

7.4 Initial / Non routine stability study

In case of change in site, new drug product, scale up, Process validation batches, change control or any incidence required the stability study incorporate under the non routine stability study. Three consecutive batches shall be kept for Accelerated and Long Term stability study. (In case of different brand name packed of same generic product, Stability study of one brand can be applicable to all brand name products having same primary packing material for non routine study except incident and change control). The stability condition study and frequency of stability study can be modified in case of non routine stability study base on case to case requirement with reference documents.

7.5 Total sampling quantity to be calculated based on test wise quantity with number of test and stations analyzed. Additional two station quantity shall be kept in both conditions of stability study for additional or OOS case study (if any).

7.6 Samples shall be stored as per labeled storage condition until incubation. If incubation of the stability samples is delayed by 30 days or more, initial (0 month) analysis shall be done again before incubation.

7.7 Tolerance for testing from the due date of analysis shall + 07 days for stability station up to 3M, + 15 days for stability station of 6M, +30 days for stability station of 9M and onwards. After due date sample should be stored at specified labeled storage condition.

7.0 GENERAL INSTRUCTION:

7.8 In case of delay in analysis, authorization in deviation form shall be taken from dept. head. Any significant change and out of the specification results shall be intimated to the Head-QC and to raise OOS with immediate effect. Head -QC shall investigate the out of specification (OOS) results according to the SOP.

7.9 If significant change or OOS findings are failing in case of Accelerated condition than it is required to increase the frequency of study from next batch. If the long term stability study failing, the joint decision shall be taken to recall of product/ Revision of Formulation/ primary packing material/ Change in storage condition Or suggested CAPA shall be followed as addressed in OOS report for further action plan.

7.10 In case of change in specification or test procedure of running stability study shall be handled with change control form and to be address with impact analysis and action plan case to case basis.

7.3 Training Record

7.3.1 To train personnel involved in the execution of stability study on following topics. Purpose, Description of Detail of methodology for execution of stability study and Acceptance criteria, Documentation.

7.4 Documentation

7.4.1 All documentation work shall be completed concurrently during execution of the stability study. However the protocol does not define the sequence of the test/ documentation to be carried out.

7.4.2 Use indelible blue ink for the recording.

7.4.3 Do not leave any blank space in report if applicable.

7.4.4 Correct the wrong entry by drawing single line through incorrect data, recording the correct data and then signing and dating the change.

7.4.5 Enter "N/A" in space that is not applicable.

7.4.6 During execution of the protocol any deviation must be reported.

8.0 VALIDATION PROGRAM

8.1 Primary Packaging material and source of API for Amoxicillin For Oral Suspension USP 250mg

8.2 Storage condition of stability study.

8.3 Objective, test, method of analysis, acceptance criteria and procedure for accelerated stability study.

8.4 Objective, test, method of analysis, acceptance criteria and procedure for long term stability study.

8.4 Deviations

8.5 OOS

8.6 Criteria for non routine stability study

8.7 Conclusion

9.0 VALIDATION PROGRAM

9.1 Primary Packaging material and source of API for Amoxicillin For Oral Suspension USP 250mg

Primary Packing material

Sr. No.	Brand Products	Description of Primary Packing Material
1	Amoxicillin For Oral Suspension USP 250mg	60 ml Amber Glass Bottle
Label Storage Condition of Product:		Do not store above 25°C. Keep the container tightly closed

Source of API

Name of API	Name of Approved Vendor
Amoxicillin USP (As Trihydrate)	Aurobindo Pharma Ltd.

9.2 Storage condition of stability study.

Study	Storage Condition
Routine/Ongoing study	$30^0C \pm 2^0C$ / 65% RH ± 5% RH
Non routine/Initial study	$30^0C \pm 2^0C$ / 65% RH ± 5% RH $40^0C \pm 2^0C$ / 75% RH ± 5% RH

9.3 Objective: To evaluate Amoxicillin For Oral Suspension USP 250mg for a physical, chemical and microbiological property varies with time under the influence of a variety of environmental factor i.e. Accelerated condition stability study $40^0C \pm 2^0C$ / 75% RH ± 5% RH.

9.3.1 **Test, Acceptance criteria and method of analysis.**

(All brand products mentioned in Annexure-IV (Manufactured from one Generic product and having same primary packaging material) have same test, MOA and specification limits under shelf life specification, so the batches shall test for stability study with respective one specification and report result could be prepared with data

replication for all mentioned product in annexure – IV individually)

Sr. No.	Brand Name of Product:	Test and Acceptance Criteria	Method of Analysis
1	Amoxicillin For Oral Suspension USP 250mg	Shelf Life specification No.: SP/BQE442SL-0	MOA No.: MOA/ BQE442SL-0

*** For further Brand Name of Products, refer Annexure IV**

9.3.2 **Procedure:**

9.3.2.1 Accelerated stability study to be performed at condition 40°C± 2°C/75% RH ± 5% RH.

9.3.2.2 Accelerated stability study shall be performed to include initial and 3rd and 6th month (0, 3, 6M) stability study.

9.3.2.3 Stability study shall be followed and data to be documented as per protocol and standard operating procedure for stability study.

9.3.2.4 Number of test, acceptance criteria and method of analysis shall followed as per reference specification number and MOA specification number as above.

9.3.2.5 5% change in assay and other tests result if found out of specification shall be considered as significant change. Incase of significant change shall be evaluated with increase in frequency and out of specification results shall be evaluated by OOS. Additionally suggested CAPA of OOS shall follow to handle significant change criteria.

9.3.2.6 The test results shall be reported with all results, conclusion in format for report of stability study. (Refer Annexure 3)

9.0 VALIDATION PROGRAM

9.4 Objective: To evaluate **Amoxicillin For Oral Suspension USP 250mg** for a physical, chemical and microbiological property varies with time under the variety of environmental factor i.e. Long term stability study $30^0C \pm 2^0C$ and 65% RH ± 5% RH.

9.4.1 **Test, Acceptance criteria and method of analysis.**

(All brand products mentioned in Annexure-IV (Manufactured from one Generic product and having same primary packaging material) have same test, MOA and specification limits under shelf life specification, so the batches shall test for stability study with respective one specification and report result could be prepared with data replication for all mentioned product in annexure – IV individually)

Sr. No.	Brand Name of Product:	Test and Acceptance Criteria	Method Of Analysis
1	Amoxicillin For Oral Suspension USP 250mg	Shelf Life specification No.: SP/BQE442SL-0	MOA No.: MOA/ BQE442SL-0

*** For further Brand Name of Products, refer Annexure IV**

9.4.2 **Procedure:**

9.4.2.1 Real time stability study to be performed at condition $30^0C \pm 2^0C$/65% RH ± 5% RH.

9.4.2.2 Long term storage condition should normally be every 3 months over the first year, every 6 months over the second year, and annually thereafter so, Long Term stability study shall be performed to include initial and 3, 6, 9, 12, 18 and 24 month station/Time point.

9.4.2.3 Stability study shall be followed and data to be documented as per protocol and standard operating procedure for stability study.

9.4.2.4 Number of test, acceptance criteria and method of analysis shall followed as per reference specification number and MOA specification number as above.

9.4.2 **Procedure:**

9.4.2.5 If OOS findings are failing in case of long term stability study, the joint decision shall be taken to recall of product/ Revision of Formulation/ primary packing material/ Change in storage condition. Or suggested CAPA shall be followed as addressed in OOS report for further action plan

9.4.2.6 The test results shall be reported with all results, conclusion in format for report of stability study. (Refer Annexure 3)

9.0 VALIDATION PROGRAM

9.5 Deviations:

Any deviations from protocol and process for stability shall be documented in the process validation report, authorized and corrected.

9.6 OOS:

If any OOS found shall be documented, investigated and authorized CAPA shall be implemented.

9.7 Non Routine Stability Study to be performed in case of:

Change in formulation

Change in primary pkg. material

Change in process or critical process parameters

Change in critical mfg. equipment

Change in vendor of API

9.8 Conclusion:

Conclusion shall address in stability study report for declaration of stability of product in particular condition till specific period of study.

10. DOCUMENT HISTORY

REVISION	DESCRIPTION OF CHANGES	EFFECTIVE DATE
00	New	04/01/2011

11. ANNEXURE

11.1 ANNEXURE 1: Stability Study Matrix for Accelerated Condition

11.2 ANNEXURE 2: Stability Study Matrix for Long Term Condition

11.3 ANNEXURE 3: Report Format for Stability Study

11.4 ANNEXURE 4: List of Applicability of Stability Study Protocol to Brand Name of Products.

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND. (GUJ.)	DEPARTMENT	Doc. No.	BQE442
	QUALITY CONTROL	Revision	00
		Supersedes	NEW
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TITLE	STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG ANNEXURE 1: STABILITY STUDY MATRIX FOR ACCELERATED CONDITION		

SR. NO.	NAME OF TEST	INITIAL	ACCELERATED CONDITION	
		0 M	3M	6M
1	DESCRIPTION	√	√	√
2	WEIGHT PER ML	√	√	√
3	pH	√	√	√
4	WATER	√	√	√
5	ASSAY (AMOXICILLIN)	√	√	√
6	ASSAY OF (AMOXICILLIN) AFTER RECONSTITUTION SUSPENSION WITHIN 7 DAYS	√	√	√
7	MICROBIAL PURITY	√	√	√
SUB TOTAL		-	3	3
TOTAL (Sub Total + OOS Samples)		9 Bottles		

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND. (GUJ.)	DEPARTMENT	Doc. No.	BQE442
	QUALITY CONTROL	Revision	00
		Supersedes	NEW
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TITLE	STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG ANNEXURE 2: STABILITY STUDY MATRIX FOR LONG TERM CONDITION		

SR. NO.	NAME OF TEST	INITIAL	LONG TERM CONDITION					
		0 M	3 M	6 M	9 M	12 M	18 M	24 M
1	DESCRIPTION	√	√	√	√	√	√	√
2	WEIGHT PER ML	√	√	√	√	√	√	√
3	pH	√	√	√	√	√	√	√
4	WATER	√	√	√	√	√	√	√
5	ASSAY (AMOXICILLIN)	√	√	√	√	√	√	√
6	ASSAY OF (AMOXICILLIN) AFTER RECONSTITUTION SUSPENSION WITHIN 7 DAYS	√	√	√	√	√	√	√
7	MICROBIAL PURITY	√	√	√	√	√	√	√
SUB TOTAL		-	3	3	3	3	3	3
TOTAL (Sub Total + OOS Samples)		21 Bottles						

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Authorized By QA: Reviewed

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/ BQE442
	QUALITY CONTROL	Revision	00
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TITLE	STABILITY STUDY REPORT FORMAT		

ACCELERATED STABILITY STUDY

Name of Product:	Amoxicillin for Oral Suspension USP 250 Mg	**Storage Condition**	40°C± 2°C /75% RH ± 5% RH.	**Mfg. Date**	JAN 2011
				Exp. Date	DEC 2012
Label Claim	After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg; Excipients Q.S; Colour: Erythrosine	**Packing details:**	60 ml Amber Glass Bottle	**Batch size**	10000 Bottles
		Sample Qty.:	9 bottles	**Date of incubation**	04/01/2011
Batch No. :	BQB087A11	**API Source:**	Amoxicillin USP (As Trihydrate) : Aurobindo Pharma Ltd.	**Period**	6 Months

Test	Specification	Initial	3 Month	6 Month
Description	White to Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.151 gm/ml	1.155 gm/ml	1.148 gm/ml
pH	Between 5.0 to 7.5	5.41	5.71	5.91
Water	NMT 3.0%	1.35%	1.51%	1.75%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.19%	99.23%	98.32%
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.18%	97.68%	96.84%
Microbial purity	1) TAMC: NMT 10^3 CFU/g 2)TYMC : NMT10^2 CFU/g 3) E.coli: Absent	1) 39 CFU/g 2) Nil 3) Absent	1) 43 CFU/g 2) Nil 3) Absent	1) 48 CFU/g 2) Nil 3) Absent
Protocol No.	**SP/BQE442**			
Conclusion:	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Remark	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			

Prepared By :	Checked By :	Approved By :
Date: 12/07/2011	Date: 12/07/2011	Date: 12/07/2011

LONG TERM STABILITY STUDY

Name of Product:	Amoxicillin for Oral Suspension USP 250 Mg	**Storage Condition**	30°C± 2°C /65% RH ± 5% RH	**Mfg. Date**	JAN 2011
				Exp. Date	DEC 2012
Label Claim	After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg Excipients Q.S Colour: Erythrosine	**Packing details:**	60 ml Amber Glass Bottle	**Batch size**	10000 Bottles
		Sample Qty.:	21 bottles	**Date of incubation**	04/01/2011
Batch No. :	BQB087A11	**API Source:**	Amoxicillin USP (As Trihydrate) : Aurobindo Pharma Ltd.	**Period**	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.151 gm/ml	1.149 gm/ml	1.151 gm/ml	1.153 gm/ml	1.155 gm/ml	1.158 gm/ml	1.1o2 gm/ml
pH	Between 5.0 to 7.5	5.41	5.44	5.45	5.48	5.51	5.54	5.59
Water	NMT 3.0%	1.35%	1.39%	1.42%	1.44%	1.47%	1.52%	1.55%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.19%	99.35%	99.08%	98.64%	97.98%	97.64%	97.05%

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.18%	98.07%	97.85%	97.53%	97.19%	96.88%	96.52%
Microbial purity	1) TAMC: NMT 10^3 CFU/g 2)TYMC : NMT10^2 CFU/g 3) E.coli: Absent	1) 39 CFU/g 2) Nil 3) Absent	1) 40 CFU/g 2) Nil 3) Absent	1) 41 CFU/g 2) Nil 3) Absent	1)43 CFU/g 2) Nil 3) Absent	1) 44 CFU/g 2) Nil 3) Absent	1) 46 CFU/g 2) Nil 3) Absent	1) 48 CFU/g 2) Nil 3) Absent

Protocol No.	SP/BQE442
Conclusion:	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.
Remark	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.

Prepared By :	Checked By :	Approved By :
Date: 13/01/2013	Date: 13/01/2013	Date: 13/01/2013

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TITLE	STABILITY STUDY REPORT FORMAT		

ACCELERATED STABILITY STUDY

Name of Product:	Amoxicillin for Oral Suspension USP 250 Mg	**Storage Condition**	40°C± 2°C /75% RH ± 5% RH.	**Mfg. Date** **Exp. Date**	JAN 2011 DEC 2012
Label Claim	After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg Excipients Q.S Colour: Erythrosine	**Packing details:**	60 ml Amber Glass Bottle	**Batch size**	10000 Bottles
		Sample Qty.:	9 bottles	**Date of incubation**	18/01/2011
Batch No. :	**BQB088A11**	**API Source:**	Amoxicillin USP (As Trihydrate) : Aurobindo Pharma Ltd.	**Period**	6 Months

Test	Specification	Initial	3 Month	6 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.138 gm/ml	1.160 gm/ml	1.158 gm/ml
pH	Between 5.0 to 7.5	5.41	5.65	5.78
Water	NMT 3.0%	1.41%	1.64%	1.79%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.51%	99.17%	98.03%
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	97.64%	97.49%	96.15%
Microbial purity	1) TAMC: NMT 10^3 CFU/g 2)TYMC : NMT10^2 CFU/g 3) E.coli: Absent	1) 36 CFU/g 2) Nil 3) Absent	1) 42 CFU/g 2) Nil 3) Absent	1) 46 CFU/g 2) Nil 3) Absent
Protocol No.	**SP/BQE442**			
Conclusion:	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Remark	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			

Prepared By :	Checked By :	Approved By :
Date: 26/07/2011	Date: 26/07/2011	Date: 26/07/2011

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Authorized By QA:

LONG TERM STABILITY STUDY

Name of Product:	Amoxicillin for Oral Suspension USP 250 Mg	**Storage Condition**	30°C± 2°C /65% RH ± 5% RH.	**Mfg. Date**	JAN 2011
				Exp. Date	DEC 2012
Label Claim	After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg Excipients Q.S Colour: Erythrosine	**Packing details:**	60 ml Amber Glass Bottle	**Batch size**	10000 Bottles
		Sample Qty.:	21 bottles	**Date of incubation**	18/01/2011
Batch No. :	BQB088A11	**API Source:**	Amoxicillin USP (As Trihydrate) : Aurobindo Pharma Ltd.	**Period**	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.138 gm/ml	1.147 gm/ml	1.158 gm/ml	1.162 gm/ml	1.151 gm/ml	1.155 gm/ml	1.145 gm/ml
pH	Between 5.0 to 7.5	5.41	5.52	5.65	5.40	5.43	5.51	5.38
Water	NMT 3.0%	1.41%	1.52%	1.54%	1.59%	1.62%	1.63%	1.68%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.51%	100.09%	99.48%	99.23%	98.64%	98.18%	97.83%

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Assay of (Amoxicillin) after reconsitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	97.64%	96.99%	96.37%	96.07%	95.66%	95.37%	94.98%
Microbial purity	1) TAMC: NMT 10^3 CFU/g 2)TYMC : NMT10^2 CFU/g 3) E.coli: Absent	1) 36 CFU/g 2) Nil 3) Absent	1) 38 CFU/g 2) Nil 3) Absent	1) 40 CFU/g 2) Nil 3) Absent	1) 42 CFU/g 2) Nil 3) Absent	1) 45 CFU/g 2) Nil 3) Absent	1) 48 CFU/g 2) Nil 3) Absent	1) 49 CFU/g 2) Nil 3) Absent

Protocol No.	**SP/BQE442**
Conclusion:	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.
Remark	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH± 5% RH.

Prepared By :	Checked By :	Approved By :
Date: 27/01/2013	Date: 27/01/2013	Date: 27/01/2013

ACCELERATED STABILITY STUDY

Name of Product:	Amoxicillin for Oral Suspension USP 250 Mg	**Storage Condition**	40°C± 2°C /75% RH ± 5% RH.	**Mfg. Date**	JAN 2011
				Exp. Date	DEC 2012
Label Claim	After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg Excipients Q.S Colour: Erythrosine	**Packing details:**	60 ml Amber Glass Bottle	**Batch size**	10000 Bottles
		Sample Qty.:	9 bottles	**Date of incubation**	26/01/2011
Batch No. :	BQB089A11	**API Source:**	Amoxicillin USP (As Trihydrate) : Aurobindo Pharma Ltd.	**Period**	6 Months

Test	Specification	Initial	3 Month	6 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.140 gm/ml	1.151 gm/ml	1.162 gm/ml
pH	Between 5.0 to 7.5	5.45	5.57	5.79
Water	NMT 3.0%	1.39%	1.68%	1.82%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.98%	99.07%	98.01%
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.26%	97.18%	96.07%
Microbial purity	1) TAMC: NMT 10^3 CFU/g 2)TYMC : NMT10^2 CFU/g 3) E.coli: Absent	1) 38 CFU/g 2) Nil 3) Absent	1) 43 CFU/g 2) Nil 3) Absent	1) 47 CFU/g 2) Nil 3) Absent
Protocol No.	**SP/BQE442**			
Conclusion:	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Remark	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			

Prepared By :	Checked By :	Approved By :
Date: 03/08/2011	Date: 03/08/2011	Date: 03/08/2011

LONG TERM STABILITY STUDY

Name of Product:	Amoxicillin for Oral Suspension USP 250 Mg	**Storage Condition**	30°C± 2°C /65% RH ± 5% RH.	**Mfg. Date**	JAN 2011
				Exp. Date	DEC 2012
	After reconstitution each 5ml contains:			**Batch size**	10000 Bottles
Label Claim	Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg Excipients Q.S Colour: Erythrosine	**Packing details:**	60 ml Amber Glass Bottle	**Date of incubation**	26/01/2011
		Sample Qty.:	21 bottles		
Batch No. :	**BQB989A11**	**API Source:**	Amoxicillin USP (As Trihydrate) : Aurobindo Pharma Ltd.	**Period**	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.140 gm/ml	1.143 gm/ml	1.148 gm/ml	1.153 gm/ml	1.158 gm/ml	1.157 gm/ml	1.159 gm/ml
pH	Between 5.0 to 7.5	5.45	5.50	5.57	5.59	5.65	5.69	5.72
Water	NMT 3.0%	1.39%	1.43%	1.49%	1.55%	1.61%	1.65%	1.69%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.98%	100.06%	99.54%	99.02%	98.51%	98.10%	97.80%

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.26%	97.68%	97.08%	96.64%	96.08%	95.68%	95.14%
Microbial purity	1) TAMC: NMT 10^3 CFU/g 2)TYMC : NMT10^2 CFU/g 3) E.coli: Absent	1) 38 CFU/g 2) Nil 3) Absent	1) 39 CFU/g 2) Nil 3) Absent	1) 41 CFU/g 2) Nil 3) Absent	1) 43 CFU/g 2) Nil 3) Absent	1) 46 CFU/g 2) Nil 3) Absent	1) 49 CFU/g 2) Nil 3) Absent	1) 50 CFU/g 2) Nil 3) Absent

Protocol No.	**SP/BQE442**
Conclusion:	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.
Remark	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.

Prepared By :	Checked By :	Approved By :
Date: 27/01/2013	Date: 27/01/2013	Date: 27/01/2013

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	BQE442
	QUALITY CONTROL	Revision	00
		Supersedes	NEW
		Page	1 of 1

TITLE	STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG ANNEXURE 4: LIST OF APPLICABILITY OF STABILITY STUDY PROTOCOL TO BRAND NAME OF PRODUCTS

This Stability Study Protocol is prepared and approved with the Generic Name of Product. The applicability of this protocol is list out for Brand name having same manufacturing formula / process as well as primary packaging material is provided or to be updated in below table.

Sr. No.	Brand Name	Product Code	Primary packing material	Shelf life specification no.	Labeled storage condition	MOA No.:	MPI No.	BPR No.	Added By	Approved By	Authorized By
1	**Amoxicillin For Oral Suspension USP 250 Mg**	BQE442	60ml amber Glass bottle	SP/BQE 442SL-0	Store in cool dark place below 25°C.	MOA/ BQE442 SL-0	BQE/MPI/ 442	BQE/BPR/ 442			

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Authorized By QA: